



## EC- Declaration of Conformity

According to Annex III of the Directive 98/79/EC of the European Parliament and of the Council of 27. October 1998

**Manufacturer:** Hitachi High-Technologies Corporation  
1-24-14 Nishi-Shinbashi  
Minato-ku, Tokyo 105-8717, Japan

**Authorised Representative:** Roche Diagnostics GmbH  
Sandhofer Straße 116  
D-68305 Mannheim, Germany

Roche Diagnostics GmbH declares that the in vitro diagnostic medical instrument

**Product name:** cobas® e 411

**Description:** Immunology analyzer for automated in-vitro analysis of patient samples with the Electro Chemiluminescence (ECL) method.

relating to this declaration, complies with the requirements of EC Directive 98/79/EC of the Council of October 27, 1998 concerning in-vitro diagnostic medical devices.

Mannheim, October 19, 2006

Roche Diagnostics GmbH

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Dr. M. Thein  
Head of Quality Management  
Centralized Diagnostics

Dr. A. Bayer  
Head of Quality Management  
Roche Instrument Center AG

### Roche Diagnostics GmbH

Roche Centralized Diagnostics  
Sandhofer Strasse 116  
D-68305 Mannheim  
Telefon +49 - 621 - 759 0  
Telefax +49 - 621 - 759 28 90

Registergericht Mannheim  
HRB 3962  
Aufsichtsrat:  
Dr. Franz B. Humer, Vorsitzender

Geschäftsführung:  
Dr. Jürgen Schwiezer, Vorsitzender  
Dr. Manfred Baier, Staffan Ek,  
Dr. Marcel Gmünder,  
Dr. Volker Pfahlert,  
Dr. Susanne Raebs,  
Peter-Claus Schiller,  
Prof. Dr. Dr. Klaus Strein